



Complete Summary

GUIDELINE TITLE

Public Health Service Task Force recommendations for use of antiretroviral drugs in pregnant HIV-1-infected women for maternal health and interventions to reduce perinatal HIV-1 transmission in the United States.

BIBLIOGRAPHIC SOURCE(S)

Perinatal HIV Guidelines Working Group. Public Health Service Task Force recommendations for use of antiretroviral drugs in pregnant HIV-1-infected women for maternal health and interventions to reduce perinatal HIV-1 transmission in the United States. Rockville (MD): U.S. Public Health Service; 2006 Oct 12. 61 p. [277 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Perinatal HIV Guidelines Working Group. Public Health Service Task Force recommendations for use of antiretroviral drugs in pregnant HIV-1-infected women for maternal health and interventions to reduce perinatal HIV-1 transmission in the United States. Rockville (MD): U.S. Public Health Service; 2006 Jul 6. 60 p. [274 references]

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references drugs for which important revised regulatory information has been released.

- [January 19, 2005, Nevirapine \(viramune\)](#): Labeling has been revised to include more information on liver toxicity associated with long term use, including a Medication Guide informing patients about risks when used for the treatment of human immunodeficiency virus (HIV).
- [October 14, 2003, Tenofovir disoproxil fumarate \(Viread®\)](#): Information distributed about a high rate of early virologic failure and emergence of nucleoside reverse transcriptase inhibitor (NRTI) resistance associated mutations with the use of the drug in a once-daily triple NRTI regimen along with didanosine enteric coated beadlets, and lamivudine.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

SCOPE

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SCOPE

DISEASE/CONDITION(S)

- Human immunodeficiency virus (HIV) infection
- Acquired immunodeficiency syndrome (AIDS)

GUIDELINE CATEGORY

Management
Prevention
Treatment

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To update the July 6, 2006 guidelines developed by the Public Health Service for the use of antiretroviral drugs to reduce the risk for perinatal human immunodeficiency virus type 1 (HIV-1) transmission
- To provide health care providers with information for discussion with HIV-1-infected pregnant women to enable such women to make an informed

decision regarding the use of antiretroviral drugs during pregnancy and use of elective cesarean delivery to reduce perinatal HIV-1 transmission

TARGET POPULATION

Human immunodeficiency virus type 1 (HIV-1)-infected pregnant women and their infants in the United States

INTERVENTIONS AND PRACTICES CONSIDERED

Antiretroviral Therapy in Human Immunodeficiency Virus-1 (HIV-1)-Infected Pregnant Women Who Have Not Received Prior Antiretroviral Therapy

1. Zidovudine (ZDV) chemoprophylaxis three-part regimen to reduce the risk for perinatal transmission of HIV: (1) oral ZDV initiated at 14 to 34 weeks' gestation and continued throughout pregnancy, (2) intravenous ZDV during labor, and (3) oral administration of ZDV to the newborn (or intravenous ZDV if oral intake is not tolerated) for 6 weeks after delivery
2. Combination of above ZDV chemoprophylaxis with additional antiretroviral drugs for intrapartum/neonatal antiretroviral prophylaxis to reduce perinatal transmission of HIV-1

Antiretroviral Therapy in HIV-1-Infected Women Receiving Antiretroviral Therapy During the Current Pregnancy

1. Continuation of current antiretroviral therapy, when pregnancy is identified after the first trimester, with addition of ZDV to the regimen
2. Counseling of women of the benefits and risks of continued antiretroviral therapy if pregnancy is recognized in first trimester
3. Stopping and reintroducing antiviral drugs simultaneously to avoid drug resistance, if therapy is stopped during first trimester

Antiretroviral Therapy in HIV-1-Infected Women in Labor Who Have Had No Prior Therapy

1. Intrapartum intravenous ZDV followed by 6 weeks of ZDV for the newborn
2. Oral ZDV and lamivudine (3TC) during labor, followed by one week of oral ZDV-3TC for the newborn
3. A single-dose nevirapine at onset on labor, followed by single dose nevirapine for the newborn at age 48 hours
4. Single-dose maternal/infant nevirapine regimen combined with intrapartum intravenous ZDV and 6-week ZDV for the newborn
5. Addition of maternal ZDV/3TC, when single-dose nevirapine is given to mother
6. Postpartum assessment (e.g., CD4+ count and HIV-1 RNA copy number) to determine potential antiretroviral therapy

Antiretroviral Therapy for Infants Born to Mothers Who Have Received No Antiviral Therapy During Pregnancy or Intrapartum

1. Initiation of 6 weeks of ZDV therapy as soon as possible after delivery
2. Combination of ZDV with other antiretroviral drugs
3. Early diagnostic testing for infant to determine if HIV-1 infection treatment should be initiated
4. Postpartum assessment (e.g., CD4+ count and HIV-1 RNA copy number) to determine potential antiretroviral therapy

General Management Practices in Pregnant HIV-1-Infected Women, Including Labor and Delivery Management, to Reduce Perinatal HIV-1 Transmission

1. Monitoring of mother for HIV-1 status (e.g., clinical assessment, CD4+ count, and HIV-1 RNA copy number) and drug side effects
2. Monitoring of infant for HIV-1 status (e.g., virologic diagnostic tests) and drug side effects (e.g., hemoglobin measurement)
3. Preconception counseling and care for HIV-1-infected women of childbearing age
4. General counseling regarding known and unknown short- and long-term benefits and risks of antiretroviral therapy for infected women and their infants
5. Resistance testing in pregnancy
6. General counseling regarding the benefit of scheduled cesarean delivery in reducing the risk of vertical transmission of HIV-1, as well as the risks to the mother associated with cesarean delivery
7. Scheduled cesarean section at 38 weeks gestation combined with intravenous ZDV initiated 3 hours prior to surgery to reduce intrapartum transmission of HIV-1
8. Postpartum follow-up of infants and mothers

Antiretroviral Therapy Considered

1. Nucleoside and nucleotide analogue reverse transcriptase inhibitors
2. Non-nucleoside reverse transcriptase inhibitors
3. Protease inhibitors
4. Fusion inhibitors

See Table 3 "Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy" in the original guideline document for specific information about recommended and alternate agents, as well as drugs that are not recommended for use in pregnancy.

MAJOR OUTCOMES CONSIDERED

- Perinatal transmission of human immunodeficiency virus type 1 (HIV-1) from mother to newborn
- Adverse and teratogenic effects of drug treatment on the fetus
- Adverse effects of drug treatment on HIV-1-infected women
- Maternal viral load (HIV-1 ribonucleic acid [RNA] levels)
- Complications of cesarean delivery

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review
Review of Published Meta-Analyses

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Combination Antiretroviral Therapy and Pregnancy Outcome

Data are conflicting as to whether receipt of combination antiretroviral therapy during pregnancy is associated with adverse pregnancy outcomes such as preterm delivery. Until more information is known, it is recommended that human immunodeficiency virus-1 (HIV-1)-infected pregnant women who are receiving combination therapy for treatment of their HIV-1 infection should continue their provider-recommended regimen. They should receive careful, regular monitoring for pregnancy complications and for potential toxicities.

Nevirapine and Hepatic/Rash Toxicity

Although deaths due to hepatic failure have been reported in HIV-infected pregnant women receiving nevirapine as part of a combination antiretroviral regimen, it is unknown if pregnancy increases the risk of hepatotoxicity in women receiving nevirapine or other antiretroviral drugs. Women initiating nevirapine with CD4⁺ counts >250 cells/mm³, including pregnant women receiving antiretroviral drugs solely for prevention of transmission, have an increased risk of developing symptomatic, often rash-associated, nevirapine-related hepatotoxicity, which can be severe, life-threatening, and in some cases fatal. Nevirapine should therefore be used as a component of a combination regimen in this setting only if the benefit clearly outweighs the risk. Regardless of maternal CD4⁺ cell count, if nevirapine is used, health care providers should be aware of this potential complication and should conduct frequent and careful monitoring of clinical symptoms and hepatic transaminases (i.e., alanine aminotransferase [ALT] and aspartate aminotransferase [AST]), particularly during the first 18 weeks of therapy. In patients with pre-existing liver disease, monitoring should be performed more frequently when initiating therapy, and then monthly. Transaminase levels should be checked in all women who develop a rash while receiving nevirapine. Patients who develop suggestive clinical symptoms accompanied by elevation in serum transaminase levels (ALT and/or AST), or who have asymptomatic but severe transaminase elevations, should stop nevirapine and not receive nevirapine therapy in the future. Hepatic toxicity has not been seen in women receiving single dose nevirapine during labor for prevention of perinatal transmission of HIV-1. Women who enter pregnancy on nevirapine regimens and are tolerating them well may continue therapy, regardless of CD4⁺ count.

Preconceptional Counseling and Care for HIV-1-Infected Women of Childbearing Age

The Centers for Disease Control and Prevention (CDC), the American College of Obstetrics and Gynecology (ACOG), and other national organizations recommend offering all women of childbearing age the opportunity to receive preconception counseling and care as a component of routine primary medical care. The purpose of preconception care is to improve the health of each woman prior to conception by identifying risk factors for adverse maternal or fetal outcome, providing education and counseling targeted to the patient's individual needs, and treating or stabilizing medical conditions to optimize maternal and fetal outcomes. Preconception care is not a single clinical visit, but rather a process of ongoing care and interventions integrated into primary care to address the needs of women during the different stages of reproductive life. Because more than half of all pregnancies are unintended, it is important that preconception care be integrated into routine health visits. Therefore, HIV care providers who routinely care for women of reproductive age play an important role in promoting preconception health.

The fundamental principles of preconception counseling and care have been outlined by the CDC Preconception Care Work Group (see the NGC summary of the CDC guideline: [Recommendations to Improve Preconception Health and Health Care](#)). In addition to the general components of preconception counseling and care that are appropriate for all women of reproductive age, HIV-1-infected women have specific needs that should be addressed. Since many women infected with HIV-1 are aware of their HIV status prior to pregnancy, there may be opportunities to address issues that impact pregnancy prior to conception during routine medical care for their HIV disease. In addition to those outlined by the CDC Preconception Care Work Group, the following components of preconception counseling and care are recommended for HIV-infected women:

The following components of preconceptional counseling are recommended for HIV-1-infected women:

- Select effective and appropriate contraceptive methods to reduce the likelihood of unintended pregnancy. Providers should be aware of potential interactions of antiretroviral drugs with hormonal contraceptives that could lower contraceptive efficacy (See the [Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents](#), Tables 21a and 21b.)
- Counsel on safe sexual practices that prevent HIV transmission to sexual partners and protect women from acquiring sexually transmitted diseases and the potential to acquire more virulent or resistant HIV strains.
- Counsel on eliminating alcohol, illicit drug use, and cigarette smoking.
- Educate and counsel women about risk factors for perinatal HIV transmission, strategies to reduce those risks, and potential effects of HIV or treatment on pregnancy course and outcomes.
- When prescribing antiretroviral treatment to women of childbearing potential, considerations should include regimen effectiveness for treatment of HIV disease and the drugs' potential for teratogenicity should pregnancy occur. Women who are planning to get pregnant should strongly consider use of antiretroviral regimens that do not contain efavirenz or other drugs with teratogenic potential, as well as regimens that are effective in preventing mother-to-child transmission.
- Attain a stable, maximally suppressed maternal viral load prior to conception in women who are on antiretroviral therapy and want to get pregnant.

- Evaluate and control for therapy-associated side effects which may adversely impact maternal-fetal health outcomes (e.g., hyperglycemia, anemia, hepatic toxicity).
- Evaluate for appropriate prophylaxis for opportunistic infections and administration of medical immunizations (e.g., influenza, pneumococcal, or hepatitis B vaccines) as indicated.
- Encourage sexual partners to receive HIV testing and counseling and appropriate HIV care if infected.
- Counsel regarding available reproductive options, such as intrauterine or intravaginal insemination, that prevent HIV exposure to an uninfected partner; expert consultation is recommended.
- Breastfeeding by HIV-infected women is not recommended in the U.S. due to risk of HIV transmission.

General Principles Regarding The Use Of Antiretroviral Agents In Pregnancy

Medical care of the HIV-1 infected pregnant woman requires coordination and communication between the HIV specialist caring for the woman when she is not pregnant and her obstetrician. Decisions regarding use of antiretroviral drugs during pregnancy should be made by the woman after discussion with her health-care provider about the known and unknown benefits and risks of therapy. Initial evaluation of an infected pregnant woman should include an assessment of HIV-1 disease status and recommendations regarding antiretroviral treatment or alteration of her current antiretroviral regimen.

This assessment should include the following:

- a. Evaluation of the degree of existing immunodeficiency determined by CD4⁺ count
- b. Risk for disease progression as determined by the level of plasma RNA
- c. History of prior or current antiretroviral therapy
- d. Gestational age
- e. Supportive care needs

Decisions regarding initiation of therapy should be the same for women who are not currently receiving antiretroviral therapy and for women who are not pregnant, with the additional consideration of the potential impact of such therapy on the fetus and infant. Similarly, for women currently receiving antiretroviral therapy, decisions regarding alterations in therapy should involve the same considerations as those used for women who are not pregnant. The three-part zidovudine (ZDV) chemoprophylaxis regimen, alone or in combination with other antiretroviral agents, should be discussed with and offered to all infected pregnant women to reduce the risk for perinatal HIV-1 transmission.

Decisions regarding the use and choice of antiretroviral drugs during pregnancy are complex; several competing factors influencing risk and benefit must be weighed. Discussion regarding the use of antiretroviral drugs during pregnancy should include the following:

- a. What is known and not known about the effects of such drugs on the fetus and newborn, including lack of long-term outcome data on the use of any of the available antiretroviral drugs during pregnancy
- b. What treatment is recommended for the health of the HIV-1 infected woman
- c. The efficacy of ZDV for reduction of perinatal HIV-1 transmission

Results from preclinical and animal studies and available clinical information about use of the various antiretroviral agents during pregnancy also should be discussed (Table 2 and 3 in the original guideline document). The hypothetical risks of these drugs during pregnancy should be placed in perspective with the proven benefit of antiretroviral therapy for the health of the infected woman and the benefit of ZDV chemoprophylaxis for reducing the risk for HIV-1 transmission to her infant.

Discussion of treatment options should be noncoercive, and the final decision regarding use of antiretroviral drugs is the responsibility of the woman. Decisions regarding use and choice of antiretroviral drugs for persons who are not pregnant are becoming increasingly complicated as the standard of care moves toward simultaneous use of multiple antiretroviral drugs to suppress viral replication below detectable limits. These decisions are further complicated in pregnancy because the long-term consequences for the infant who has been exposed to antiretroviral drugs in utero are unknown. A woman's decision to refuse treatment with ZDV or other drugs should not result in punitive action or denial of care. Further, use of ZDV alone should not be denied to a woman who wishes to minimize exposure of the fetus to other antiretroviral drugs and therefore, after counseling, chooses to receive only ZDV during pregnancy to reduce the risk for perinatal transmission.

A long-term treatment plan should be developed after discussion between the patient and the health-care provider and should emphasize the importance of adherence to any prescribed antiretroviral regimen. Depending on individual circumstances, provision of support services, mental health services, and drug abuse treatment may be required. Coordination of services among prenatal care providers, primary care and HIV-1 specialty care providers, mental health and drug abuse treatment services, and public assistance programs is essential to ensure adherence of the infected woman to antiretroviral treatment regimens.

General counseling should include what is known regarding risk factors for perinatal transmission. Cigarette smoking, illicit drug use, and unprotected sexual intercourse with multiple partners during pregnancy have been associated with risk for perinatal HIV-1 transmission, and discontinuing these practices might reduce this risk. In addition, the Centers for Disease Control and Prevention (CDC) recommends that infected women in the United States refrain from breastfeeding to avoid postnatal transmission of HIV-1 to their infants through breast milk; these recommendations also should be followed by women receiving antiretroviral therapy. Passage of antiretroviral drugs into breast milk has been evaluated for only a few antiretroviral drugs. ZDV, lamivudine (3TC), and nevirapine can be detected in the breast milk of women, and didanosine (ddI), stavudine (d4T), abacavir, delavirdine, indinavir, ritonavir, saquinavir, and amprenavir can be detected in the breast milk of lactating rats. Limited data are available regarding either the efficacy of antiretroviral therapy for the prevention of postnatal transmission of HIV-1 through breast milk or the toxicity of long-term antiretroviral exposure of the infant through breast milk.

Women who must temporarily discontinue therapy because of pregnancy-related hyperemesis should not resume therapy until sufficient time has elapsed to ensure that the drugs will be tolerated. To reduce the potential for emergence of resistance, if therapy requires temporary discontinuation for any reason during pregnancy, all drugs should be stopped and reintroduced simultaneously.

Recommendations for Antiretroviral Chemoprophylaxis to Reduce Perinatal HIV-1 Transmission

Recommendations for the use of antiretroviral chemoprophylaxis to reduce the risk for perinatal transmission are based on situations that may be commonly encountered in clinical practice (see Table 4 titled "Clinical Scenarios and Recommendations for the Use of Antiretroviral Drugs to Reduce Perinatal Human Immunodeficiency Virus Type 1 [HIV-1] Transmission" in the original guideline document). These recommendations are only guidelines and flexibility should be exercised according to the patient's individual circumstances.

The antenatal dosing regimen in the Pediatric AIDS Clinical Trials Group (PACTG) 076 (100 mg administered orally five times daily) (see the table titled "Pediatric AIDS Clinical Trials Group [PACTG] 076 Zidovudine [ZDV] Regimen" below) was selected on the basis of standard ZDV dosage for adults at the time of the study. However, recent data have indicated that administration of ZDV three times daily will maintain intracellular ZDV triphosphate at levels comparable with those observed with more frequent dosing. Comparable clinical response also has been observed in some clinical trials among persons receiving ZDV twice daily. Thus, the current standard ZDV dosing regimen for adults is 200 mg three times daily or 300 mg twice daily. Because the mechanism by which zidovudine reduces perinatal transmission is not known, these dosing regimens may not have equivalent efficacy to that observed in PACTG 076. However, a regimen of two- or three-times daily is expected to increase maternal adherence to the regimen.

The recommended ZDV dosage for infants was derived from pharmacokinetic studies performed among full-term infants. Results of a pharmacokinetic study of ZDV dosing in infants <35 weeks gestation at birth (PACTG 331) indicated that the appropriate dose of ZDV for preterm infants is 1.5 mg/kg/dose intravenously, or 2.0 mg/kg/dose orally, every 12 hours, advancing to every 8 hours at 2 weeks of age if ≥ 30 weeks gestation at birth or at 4 weeks of age if <30 weeks gestation at birth.

Table. Pediatric AIDS Clinical Trials Group (PACTG) 076 Zidovudine (ZDV) Regimen

Time of Zidovudine (ZDV) Administration	Regimen
Antepartum	<p>Oral administration of 100 mg ZDV five times daily, initiated at 14 to 34 weeks' gestation and continued throughout the pregnancy</p> <p>Note: Oral ZDV administered as 200 mg three times daily or 300 mg twice daily is currently used in general clinical practice</p>

Time of Zidovudine (ZDV) Administration	Regimen
	and is an acceptable alternative regimen to 100 mg orally five times daily.
Intrapartum	During labor, intravenous administration of ZDV in a one-hour initial dose of 2 mg/kg body weight, followed by a continuous infusion of 1 mg/kg body weight/hour until delivery.
Postpartum	Oral administration of ZDV to the newborn (ZDV syrup at 2 mg/kg body weight/dose every 6 hours) for the first 6 weeks of life, beginning at 8 to 12 hours after birth. Note: Intravenous dosage for full-term infants who cannot tolerate oral intake is 1.5 mg/kg body weight intravenously every 6 hours. ZDV dosing for infants <35 weeks gestation at birth is 1.5 mg/kg/dose intravenously, or 2.0 mg/kg/dose orally, every 12 hours, advancing to every 8 hours at 2 weeks of age if >30 weeks gestation at birth or at 4 weeks of age if <30 weeks gestation at birth.

Clinical Situations and Recommendations for Use of Antiretroviral Prophylaxis

Scenario No. 1: HIV-1-Infected Pregnant Women Who Have Not Received Prior Antiretroviral Therapy

- Pregnant women with HIV-1 infection must receive standard clinical, immunologic, and virologic evaluation. Recommendations for initiation and choice of antiretroviral therapy should be based on the same parameters used for persons who are not pregnant, although the known and unknown risks and benefits of such therapy during pregnancy must be considered and discussed.
- The three-part zidovudine (ZDV) chemoprophylaxis regimen, initiated after the first trimester, is recommended for all pregnant women with HIV-1 infection regardless of antenatal HIV-1 RNA copy number to reduce the risk for perinatal transmission.
- The combination of ZDV chemoprophylaxis with additional antiretroviral drugs for treatment of HIV-1 infection is recommended for infected women whose clinical, immunologic, or virologic status requires treatment or whose HIV-1 RNA >1,000 copies/mL regardless of their clinical or immunologic status, and can be considered for women with HIV-1 RNA <1,000 copies/mL.
- Women who are in the first trimester of pregnancy may consider delaying initiation of therapy until after 10 to 12 weeks' gestation.

Scenario No. 2: HIV-1-Infected Women Receiving Antiretroviral Therapy During the Current Pregnancy

- HIV-1-infected women receiving antiretroviral therapy whose pregnancy is identified after the first trimester should continue therapy. ZDV should be a component of the antenatal antiretroviral treatment regimen after the first trimester whenever possible, although this may not always be feasible.

- Women receiving antiretroviral therapy in whom pregnancy is recognized during the first trimester should be counseled regarding the benefits and potential risks of antiretroviral administration during this period, and continuation of therapy should be considered. If therapy is discontinued during the first trimester, all drugs should be stopped and reintroduced simultaneously to avoid the development of drug resistance.
- Regardless of the antepartum antiretroviral regimen, ZDV administration is recommended during the intrapartum period and for the newborn.

Scenario No. 3: HIV-1-Infected Women in Labor Who Have Had No Prior Therapy

- Several effective regimens are available for women who have had no prior therapy (see Table 5 titled "Comparison of Intrapartum/Postpartum Regimens for HIV-1-Infected Women in Labor Who Have Had No Prior Antiretroviral Therapy [Scenario #3]" in the original guideline document). These include: (1) intrapartum intravenous ZDV followed by six weeks of ZDV for the newborn; (2) oral ZDV and lamivudine (3TC) during labor, followed by one week of oral ZDV-3TC for the newborn; (3) a single dose of nevirapine at the onset of labor followed by a single dose of nevirapine for the newborn at age 48 hours; and (4) the single-dose maternal/infant nevirapine regimen combined with intrapartum intravenous ZDV and six week ZDV for the newborn.
- If single-dose nevirapine is given to the mother, alone or in combination with ZDV, consideration should be given to adding maternal ZDV/3TC starting as soon as possible (intrapartum or immediately postpartum) and continuing for 3 to 7 days, which may reduce development of nevirapine resistance.
- In the immediate postpartum period, the woman should have appropriate assessments (e.g., CD4⁺ count and HIV-1 RNA copy number) to determine whether antiretroviral therapy is recommended for her own health.

Scenario No. 4: Infants Born to Mothers Who Have Received No Antiretroviral Therapy During Pregnancy or Intrapartum

- The 6-week neonatal ZDV component of the ZDV chemoprophylactic regimen should be discussed with the mother and offered for the newborn.
- ZDV should be initiated as soon as possible after delivery, preferably within 6 to 12 hours of birth.
- Some clinicians may use ZDV in combination with other antiretroviral drugs, particularly if the mother is known or suspected to have ZDV-resistant virus. However, the efficacy of this approach for prevention of transmission has not been proven in clinical trials, and appropriate dosing regimens for neonates are incompletely defined for many drugs.
- In the immediate postpartum period, the woman should undergo appropriate assessments (e.g., CD4⁺ count and HIV-1 RNA copy number) to determine if antiretroviral therapy is required for her own health. The infant should undergo early diagnostic testing so that if he or she is HIV-1 infected, treatment can be initiated as soon as possible.

Antiretroviral Drug Resistance and Resistance Testing in Pregnancy

- HIV drug resistance testing is recommended for:

- a. All pregnant women not currently receiving antiretrovirals, before starting treatment or prophylaxis
 - b. All pregnant women receiving antenatal antiretroviral therapy who have virologic failure with persistently detectable HIV RNA levels or who have sub-optimal viral suppression after initiation of antiretroviral therapy
- For optimal prevention of perinatal transmission, empiric initiation of antiretroviral therapy before results of resistance testing are available may be warranted, with adjustment as needed after the results are available.
- The use of highly active antiretroviral combination therapy to maximally suppress viral replication during pregnancy is the most effective strategy to prevent the development of resistance and to minimize the risk of perinatal transmission.
- All pregnant women should be counseled about the importance of adherence to prescribed antiretroviral medications to reduce the potential for development of resistance.
- The addition of single-dose maternal/infant nevirapine (NVP) to an ongoing highly active combination antiretroviral therapy regimen does not provide additional efficacy in reducing perinatal transmission and may result in NVP drug resistance in the mother, and is therefore not recommended.
- NVP-based combination therapy should not be initiated in women with CD4 count >250 cells/mm³ unless the benefit clearly outweighs the risk due to concern about increased risk of hepatic toxicity (see "Nevirapine and Hepatic/Rash Toxicity" in the original guideline document). However, some pregnant women may receive an NVP-based combination antiretroviral therapy regimen for prophylaxis only, with plans to discontinue therapy after delivery. In this situation, consideration should be given to continuing the nucleoside analogue agents for 3 to 7 days after stopping NVP to minimize the risk of NVP resistance.
- Women who have documented ZDV resistance and are on regimens that do not include ZDV for their own health should still receive intravenous ZDV during labor whenever possible, along with their established antiretroviral regimens, and oral ZDV for their infants according to the PACTG 076 protocol. For women who are receiving a stavudine-containing regimen, stavudine should be discontinued during labor while intravenous ZDV is being administered.
- The optimal prophylactic regimen for newborns of women with antiretroviral (ARV) resistance is unknown. Therefore, ARV prophylaxis for an infant born to a woman with known or suspected drug resistance should be determined in consultation with a pediatric HIV specialist, preferably before delivery.

Management of Antiretroviral Drug Resistance during Pregnancy

For women who have documented ZDV resistance and whose antepartum regimen does not include ZDV, intravenous ZDV during labor should still be administered whenever possible. If the woman's antepartum regimen includes stavudine, which may be antagonistic to ZDV, stavudine should be stopped during the intrapartum period and restarted after delivery. Other antiretrovirals should be continued orally during labor to the extent possible. Oral ZDV for six weeks should also be administered to the infant. For an infant born to a woman with known ZDV resistant virus, many clinicians would choose to provide additional antiretroviral agents to the infant in combination with ZDV. Such a decision must be

accompanied by a discussion with the woman of the potential benefits and risks of this approach and the lack of data to address its efficacy and safety. The optimal prophylactic regimen for newborns of women with antiretroviral drug resistant virus is unknown. Therefore, antiretroviral prophylaxis for the infant born to a woman with known or suspected drug resistant virus should be determined with a pediatric HIV specialist, preferably before delivery.

Perinatal HIV-1 Transmission and Mode of Delivery

Recommendations

Considerations related to counseling of the HIV-1-infected pregnant woman regarding risks for vertical transmission of HIV-1 to the fetus/neonate and to the obstetric care of such women include the following:

- Efforts to maximize the health of the pregnant woman, including the provision of highly active combination antiretroviral therapy, can be expected to correlate with both reduction in viral load and low rates of vertical transmission. At a minimum for the reduction of perinatal HIV-1 transmission, ZDV prophylaxis according to the PACTG 076 regimen is recommended unless the woman is intolerant of ZDV.
- Plasma HIV-1 RNA levels should be monitored during pregnancy according to the guidelines for management of HIV-1-infected adults. The most recently determined viral load value should be used when counseling a woman regarding mode of delivery.
- Perinatal HIV-1 transmission is reduced by scheduled cesarean delivery among women with unknown HIV-1 RNA levels who are not receiving antiretroviral therapy or are receiving only ZDV for prophylaxis of perinatal transmission. Plasma HIV-1 RNA levels were not available in these studies to assess the potential benefit among women with low plasma HIV-1 RNA levels.
- Women with HIV-1 RNA levels >1,000 copies/mL should be counseled regarding the potential benefit of scheduled cesarean delivery in reducing the risk of vertical transmission. The benefit among women on highly active antiretroviral therapy (HAART) is unproven.
- Data are insufficient to evaluate the potential benefit of cesarean delivery for neonates of antiretroviral-treated women with plasma HIV-1 RNA levels below 1,000 copies/mL. Given the low rate of transmission among this group, it is unlikely that scheduled cesarean delivery would confer additional benefit in reduction of transmission.
- Management of women originally scheduled for cesarean delivery who present with ruptured membranes or in labor must be individualized based on duration of rupture, progress of labor, plasma HIV-1 RNA level, current antiretroviral therapy, and other clinical factors. It is not clear that cesarean delivery after rupture or onset of labor provides benefit in reducing transmission.
- Women should be informed of the risks associated with cesarean delivery; these risks to the woman should be balanced with potential benefits expected for the neonate.
- Women should be counseled regarding the limitations of the current data. The woman's autonomy to make an informed decision regarding route of delivery should be respected and honored.

Clinical Situations

The following recommendations are based on various hypothetical situations that may be encountered in clinical practice (see Table 7 titled "Clinical Scenarios and Recommendations Regarding Mode of Delivery to Reduce Perinatal Human Immunodeficiency Virus Type 1 [HIV-1] Transmission" in the original guideline document). These recommendations are only guidelines, and flexibility should be exercised according to the patient's individual circumstances.

Scenario A: HIV-1-infected women presenting in late pregnancy (after approximately 36 weeks of gestation), known to be HIV-1 infected but not receiving antiretroviral therapy, and whose results for HIV-1 RNA level and lymphocyte subsets are pending but unlikely to be available before delivery.

- Therapy options should be discussed in detail. Antiretroviral therapy, including at least the PACTG 076 ZDV regimen, should be initiated. In counseling, the woman should be informed that scheduled cesarean section is likely to reduce the risk of transmission to her infant. She should also be informed of the increased risks to her of cesarean delivery, including increased rates of postoperative infection, anesthesia risks, and other surgical risks.
- If cesarean delivery is chosen, the procedure should be scheduled at 38 weeks of gestation, based on the best available clinical information. When scheduled cesarean section is performed, the woman should receive continuous intravenous ZDV infusion beginning 3 hours before surgery, and her infant should receive 6 weeks of ZDV therapy after birth. Options for continuing or initiating combination antiretroviral therapy after delivery should be discussed with the woman as soon as her viral load and lymphocyte subset results are available.

Scenario B: HIV-1-infected women who began prenatal care early in the third trimester, are receiving highly active combination antiretroviral therapy, and have an initial virologic response, but have HIV-1 RNA levels that remain substantially over 1,000 copies/mL at 36 weeks of gestation.

- The current combination antiretroviral regimen should be continued because the HIV-1 RNA level is declining appropriately. The woman should be informed that although her HIV-1 RNA level is responding to the antiretroviral therapy, it is unlikely that it will reach <1,000 copies/mL before delivery. Therefore, scheduled cesarean delivery may provide additional benefit in preventing intrapartum transmission of HIV-1. She should also be informed of the increased risks to her of cesarean delivery, including increased rates of postoperative infection, anesthesia risks, and surgical risks.
- If she chooses scheduled cesarean section, it should be performed at 38 weeks' gestation, and intravenous ZDV should be started at least 3 hours before surgery. Other antiretroviral medications should be continued on schedule as much as possible before and after surgery. The infant should receive oral ZDV for 6 weeks after birth. The importance of adhering to therapy after delivery, for her own health, should be emphasized.

Scenario C: HIV-1-infected women receiving highly active combination antiretroviral therapy who have an undetectable HIV-1 RNA level at 36 weeks of gestation.

- The woman should be informed that her risk of perinatal transmission of HIV-1 with a persistently undetectable HIV-1 RNA level is low, probably 2% or less, even with vaginal delivery. Current information suggests that performing a scheduled cesarean delivery will not lower her risk further. Cesarean delivery has an increased risk of complications for the woman compared with vaginal delivery, and these risks must be balanced against the uncertain benefit of cesarean delivery in this case.

Scenario D: HIV-1-infected women who have elected scheduled cesarean delivery but present in early labor or shortly after rupture of membranes.

- Intravenous ZDV should be started immediately since the woman is in labor or has ruptured membranes.
- If cervical dilatation is minimal and a long period of labor is anticipated, the clinician may begin the loading dose of intravenous ZDV and proceed as expeditiously as possible with cesarean delivery to minimize the duration of membrane rupture and avoid vaginal delivery. Alternatively, the clinician might begin oxytocin augmentation to enhance contractions and potentially expedite delivery.
- If labor is progressing rapidly, the woman should be allowed to deliver vaginally.
- If the woman is allowed to labor, scalp electrodes and other invasive monitoring and operative delivery should be avoided if possible. Other antiretrovirals besides ZDV should be continued orally during labor. The infant should be treated with 6 weeks of ZDV therapy after birth.

Recommendations for Monitoring of Women and Their Infants

Pregnant Woman and Fetus

HIV-1-infected pregnant women should be monitored according to the same standards for monitoring HIV-1-infected persons who are not pregnant. This monitoring should include measurement of CD4⁺ counts and HIV-1 RNA levels approximately every trimester (i.e., every 3 to 4 months) to determine (a) the need for antiretroviral therapy of maternal HIV-1 disease, (b) whether such therapy should be altered, and (c) whether prophylaxis against *Pneumocystis carinii* pneumonia should be initiated.

Changes in absolute CD4⁺ count during pregnancy may reflect the physiologic changes of pregnancy on hemodynamic parameters and blood volume as opposed to a long-term influence of pregnancy on CD4⁺ count; CD4⁺ percentage is likely more stable and might be a more accurate reflection of immune status during pregnancy. Long-range plans should be developed with the woman regarding continuity of medical care and antiretroviral therapy for her own health after the birth of her infant.

Monitoring for potential complications of the administration of antiretrovirals during pregnancy should be based on what is known about the side effects of the

drugs the woman is receiving. For example, routine hematologic and liver enzyme monitoring is recommended for women receiving ZDV. Because combination antiretroviral regimens have been used less extensively during pregnancy, more intensive monitoring may be warranted for women receiving drugs other than or in addition to ZDV. For example, women receiving protease inhibitors should be monitored for development of hyperglycemia. Women, particularly those with CD4⁺ counts >250 cells/mm³, have an increased risk of developing symptomatic, rash-associated, nevirapine-associated hepatotoxicity; thus, pregnant women receiving nevirapine should have frequent and careful monitoring of transaminase levels, particularly during the first 18 weeks of treatment.

Antepartum fetal monitoring for women who receive only ZDV chemoprophylaxis should be performed as clinically indicated, because data do not indicate that ZDV use in pregnancy is associated with increased risk for fetal complications. Less is known about the effect of combination antiretroviral therapy on the fetus during pregnancy. Thus, more intensive fetal monitoring should be considered for mothers receiving such therapy, including assessment of fetal anatomy with a level II ultrasound and continued assessment of fetal growth and wellbeing during the third trimester.

Neonate

A complete blood count and differential should be performed on the newborn as a baseline evaluation before administration of ZDV. Anemia has been the primary complication of the 6-week ZDV regimen in the neonate; thus, repeat measurement of hemoglobin is required at a minimum after the completion of the 6-week ZDV regimen. If abnormal, repeat measurement should be performed at 12 weeks of age, by which time any ZDV-related hematologic toxicity should be resolved. Infants who have anemia at birth or who are born prematurely warrant more intensive monitoring.

Data are limited concerning potential toxicities in infants whose mothers have received combination antiretroviral therapy. More intensive monitoring of hematologic and serum chemistry measurements during the first few weeks of life is advised in these infants. However, it should be noted that the clinical relevance of lactate levels in the neonatal period to assess potential for mitochondrial toxicity has not been adequately evaluated.

To prevent *Pneumocystis carinii* pneumonia, all infants born to women with HIV-1 infection should begin prophylaxis at 6 weeks of age, after completion of the ZDV prophylaxis regimen. Monitoring and diagnostic evaluation of HIV-1 exposed infants should follow current standards of care. Data do not indicate any delay in HIV-1 diagnosis in infants who have received the ZDV regimen. However, the effect of combination antiretroviral therapy in the mother or newborn on the sensitivity of infant virologic diagnostic testing is unknown. Infants with negative virologic test results during the first 6 weeks of life should have diagnostic evaluation repeated after completion of the neonatal antiretroviral prophylaxis regimen.

Postpartum Follow-Up of Women

Comprehensive care and support services are important for women with HIV-1 infection and their families. Components of comprehensive care include the following medical and supportive care services:

- Primary, obstetric, pediatric and HIV-1 specialty care
- Family planning services
- Mental health services
- Substance-abuse treatment
- Coordination of care through case management for the woman, her children, and other family members

Support services may include case management, child care, respite care, assistance with basic life needs (e.g., housing, food, and transportation), and legal and advocacy services. This care should begin before pregnancy and should be continued throughout pregnancy and postpartum.

Maternal medical services during the postpartum period must be coordinated between obstetric care providers and HIV-1 specialists. Continuity of antiretroviral treatment when such treatment is required for the woman's HIV-1 infection is especially critical and must be ensured. Concerns have been raised about adherence to antiretroviral regimens during the postpartum period. Women should be counseled about the fact that the physical changes of the postpartum period, as well as the stresses and demands of caring for a new baby, can make adherence more difficult and additional support may be needed to maintain good adherence to their therapeutic antiretroviral regimen during this period. The health care provider should be vigilant for signs of depression, which may require assessment and treatment and which may interfere with adherence. Poor adherence has been shown to be associated with virologic failure, development of resistance, and decreased long-term effectiveness of antiretroviral therapy. Efforts to maintain good adherence during the postpartum period might prolong the effectiveness of therapy. See the "Adherence" sections in the NGC summary of the CDC guideline document titled [Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents](#).

All women should receive comprehensive health care services that continue after pregnancy for their own medical care and for assistance with family planning and contraception. In addition, this is a good time to review immunization status and update vaccines, assess the need for prophylaxis against opportunistic infections, and re-emphasize safer sex practices.

Data from PACTG 076 and 288 do not indicate adverse effects through 4 years postpartum among women who received ZDV during pregnancy. Women who have received only ZDV chemoprophylaxis during pregnancy should receive appropriate evaluation to determine the need for antiretroviral therapy during the postpartum period.

Long-Term Follow-Up of Infants

Data remain insufficient to address the effect that exposure to ZDV or other antiretroviral agents in utero might have on long-term risk for neoplasia or organ system toxicities in children. Data from follow-up of PACTG 076 infants through age 6 years do not indicate any differences in immunologic, neurologic, and

growth parameters between infants who were exposed to the ZDV regimen and those who received placebo, and no malignancies have been seen. There are conflicting data regarding whether mitochondrial dysfunction is associated with perinatal antiretroviral exposure. Mitochondrial dysfunction should be considered in uninfected children with perinatal antiretroviral exposure who present with severe clinical findings of unknown etiology, particularly neurologic findings.

Continued evaluation of early and late effects of in utero antiretroviral exposure is ongoing through several mechanisms, including a long-term follow-up study in the PACTG 219C, natural history studies, and HIV/AIDS surveillance conducted by state health departments and the Centers for Disease Control and Prevention (CDC). Because most of the available follow-up data relate to in utero exposure to antenatal ZDV alone and most pregnant women with HIV-1 infection currently receive combination therapy, it is critical that studies to evaluate potential adverse effects of in utero drug exposure continue to be supported.

Innovative methods are needed to provide follow-up of infants with in utero exposure to antiretroviral drugs. Information regarding such exposure should be part of the ongoing permanent medical record of the child, particularly for uninfected children. Children with in utero antiretroviral exposure who develop significant organ system abnormalities of unknown etiology, particularly of the nervous system or heart, should be evaluated for potential mitochondrial dysfunction. Follow-up of children with antiretroviral exposure should continue into adulthood because of the theoretical concerns regarding potential for carcinogenicity of the nucleoside analog antiretroviral drugs. Long-term follow-up should include yearly physical examinations of all children exposed to antiretroviral drugs and, for adolescent females, gynecologic evaluation with Pap smears.

HIV-1 surveillance databases from states that require HIV-1 reporting provide an opportunity to collect population-based information concerning in utero antiretroviral exposure. To the extent permitted by federal law and regulations, data from these confidential registries can be used to compare with information from birth defect and cancer registries to identify potential adverse outcomes.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate use of antiretroviral drugs in pregnant human immunodeficiency virus (HIV)-1-Infected women for maternal health and interventions to reduce perinatal HIV-1 transmission in the United States
- Efforts to maximize the health of the pregnant woman, including the provision of highly active combination antiretroviral therapy, can be expected to correlate with both reduction in viral load and low rates of vertical transmission.

POTENTIAL HARMS

- Combination antiretroviral therapy and pregnancy outcome: Data are conflicting as to whether receipt of combination antiretroviral therapy during pregnancy is associated with adverse pregnancy outcomes such as preterm delivery. Until more information is known, human immunodeficiency virus type 1 (HIV-1) infected pregnant women who are receiving combination therapy for their HIV-1 infection should continue their provider-recommended regimen. They should receive careful, regular monitoring for pregnancy complications and for potential toxicities.
- Nevirapine and hepatic/rash toxicity: Increases in hepatic transaminase levels (ALT and AST) associated with rash or systemic symptoms may be observed during the first 18 weeks of treatment with nevirapine.
- Protease inhibitor therapy and hyperglycemia: Hyperglycemia, new-onset diabetes mellitus, exacerbation of existing diabetes mellitus, and diabetic ketoacidosis have been reported with receipt of protease inhibitor antiretroviral drugs by HIV-1 infected patients.
- Postpartum hemorrhage, antiretroviral drugs, and methergine use: Women experiencing postpartum hemorrhage due to uterine atony are often managed with oral or parenteral methergine as a first-line agent. However, methergine should not be coadministered with drugs that are potent CYP3A4 enzyme inhibitors, including protease inhibitors and the non-nucleoside reverse transcriptase inhibitors efavirenz and delavirdine. The concomitant use of ergotamines and protease inhibitors has been associated with exaggerated vasoconstrictive responses. When uterine atony results in excessive postpartum bleeding in women receiving protease inhibitors or efavirenz or delavirdine as a component of an antiretroviral regimen, methergine should only be used if alternative treatments (e.g., prostaglandin F 2 alpha, misoprostol, or oxytocin) are not available. If there are no alternative medications available and the need for pharmacologic treatment outweighs the risks, methergine should be used in as low a dosage and for as short a duration as possible.
- Mitochondrial toxicity and nucleoside analogue drugs: Toxicity related to mitochondrial dysfunction has been reported to occur in infected patients receiving long-term treatment with nucleoside analogues and generally has resolved with discontinuation of the drug or drugs; a possible genetic susceptibility to these toxicities has been suggested. These toxicities may be of particular concern for pregnant women and infants with in utero exposure to nucleoside analogue drugs.
- Neonatal complications: Anemia has been the primary complication of the 6-week ZDV regimen in the neonate. Data remain insufficient to address the effect that exposure to zidovudine or other antiretroviral agents in utero might have on long-term risk for neoplasia or organ-system toxicities in children. Mitochondrial dysfunction should be considered in uninfected

- children with perinatal antiretroviral exposure who present with severe clinical findings of unknown etiology, particularly neurologic findings.
- Drug resistance: Pregnancy presents some special concerns related to the development of drug resistance. Pre-existing resistance to a drug in an antiretroviral prophylaxis regimen may diminish efficacy of that regimen in preventing perinatal transmission. Development of resistance to drugs used during pregnancy for prophylaxis of perinatal transmission may limit future maternal treatment options or decrease the effectiveness of prophylactic regimens in the current pregnancy or future pregnancies. Additionally, if maternal resistance is present or develops and resistant virus is transmitted, infant treatment options may be limited.
 - Maternal complications of cesarean delivery: Among women not infected with HIV-1, maternal morbidity and mortality are greater after cesarean than after vaginal delivery. Complications, especially postpartum infections, are approximately five to seven times more common after cesarean delivery performed after labor or membrane rupture compared with vaginal delivery. Complications after scheduled cesarean delivery are more common than with vaginal delivery but less than with urgent cesarean delivery.

Data indicate that cesarean delivery is associated with a slightly greater risk of complications among HIV-1-infected women than observed among uninfected women, with the difference most notable among women with more advanced disease. Scheduled cesarean delivery for prevention of HIV-1 transmission poses a risk greater than that of vaginal delivery and less than that of urgent or emergent cesarean section. Complication rates in most studies were within the range reported in populations of HIV-1-uninfected women with similar risk factors and were not of sufficient frequency or severity to outweigh the potential benefit of reduced transmission among women at heightened risk of transmission. HIV-1-infected women should be counseled regarding the increased risks associated with cesarean delivery as well as the potential benefits based on their HIV-1 RNA levels and current antiretroviral therapy.

- Safety and toxicity of antiretroviral agents: Refer to Table 2 titled "Preclinical and Clinical Data Relevant to the Use of Antiretrovirals During Pregnancy" and Table 3 titled "Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy" in the original guideline document, as well as the companion document titled "Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy," for important and detailed information regarding the safety and toxicity of individual antiretroviral drugs and combination antiretroviral therapy in pregnancy. Both the original guideline document and the companion document are available at the [AIDSinfo Web site](#).

Subgroups Most Likely to be Harmed

Women initiating nevirapine with CD4⁺ counts >250 cells/mm³, including pregnant women receiving antiretroviral drugs solely for prevention of transmission, have an increased risk of developing symptomatic, often rash-associated, nevirapine-related hepatotoxicity, which can be severe, life-threatening, and in some cases fatal.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These recommendations have been developed for use in the United States. Although perinatal HIV-1 transmission occurs worldwide, alternative strategies may be appropriate in other countries. Policies and practices in other countries regarding the use of antiretroviral drugs for reduction of perinatal HIV-1 transmission may differ from the recommendations in this report and will depend on local considerations, including availability and cost of antiretroviral drugs, access by pregnant women to facilities for safe intravenous infusions during labor, local recommendations regarding breastfeeding by HIV-1-infected women, and alternative interventions being evaluated in that area.
- Information included in these guidelines may not represent approval by the U.S. Food and Drug Administration (FDA) or approved labeling for the particular product or indications in question. Specifically, the terms "safe" and "effective" may not be synonymous with the FDA-defined legal standards for product approval.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Foreign Language Translations
Patient Resources
Personal Digital Assistant (PDA) Downloads
Resources
Slide Presentation

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

RELATED QUALITY TOOLS

- [AIDSinfo's Drug Database for Palm PDAs](#)
- [HIV During Pregnancy, Labor and Delivery, and After Birth Fact Sheets](#)
- [A Pocket Guide to Adult HIV/AIDS Treatment: Companion to A Guide to Primary Care of People with HIV/AIDS August 2004 Edition](#)

- [AIDSinfo's HIV/AIDS Glossary for Palm PDAs](#)

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Perinatal HIV Guidelines Working Group. Public Health Service Task Force recommendations for use of antiretroviral drugs in pregnant HIV-1-infected women for maternal health and interventions to reduce perinatal HIV-1 transmission in the United States. Rockville (MD): U.S. Public Health Service; 2006 Oct 12. 61 p. [277 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

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GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Perinatal HIV Guidelines Working Group. Public Health Service Task Force recommendations for use of antiretroviral drugs in pregnant HIV-1-infected women for maternal health and interventions to reduce perinatal HIV-1 transmission in the United States. Rockville (MD): U.S. Public Health Service; 2006 Jul 6. 60 p. [274 references]

GUIDELINE AVAILABILITY

Electronic copies: Available from the [AIDSinfo Web site](#).

The guideline is also available for Palm OS or Pocket PC download from the [AIDSinfo Web site](#).

Print copies: Available from the Centers for Disease Control and Prevention, National Prevention Information Network (NPIN), P.O. Box 6003, Rockville, MD 20850. Telephone: (800) 458-5231, TTY (800)-243-7012 International number (301)-562-1098. Web site: <http://www.cdcnpin.org>. Requests for print copies can also be submitted via the [AIDSinfo Web site](#).

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Safety and toxicity of individual antiretroviral agents in pregnancy. 2006 Oct 12. 25 p. Electronic copies: Available in Portable Document Format (PDF) from the [AIDSinfo Web site](#). Also available for Palm OS or Pocket PC download from the [AIDSinfo Web site](#).
- Wortley PM, Lindegren ML, Fleming PL. Successful implementation of perinatal HIV prevention guidelines. A multistate surveillance evaluation. MMWR Recomm Rep. 2001 May 11;50(RR-6):17-28. Available from the [AIDSinfo Web site](#).

Print copies: Available from the Centers for Disease Control and Prevention, National Prevention Information Network (NPIN), P.O. Box 6003, Rockville, MD 20850. Telephone: (800) 458-5231, TTY (800)-243-7012 International number (301)-562-1098. Web site: <http://www.cdcnpin.org>. Requests for print copies can also be submitted via the [AIDSinfo Web site](#).

The following Power Point slide set based on the "Recommendations for use of antiretroviral drugs in pregnant HIV-1 infected women for maternal health and interventions to reduce perinatal HIV-1 transmission in the United States" is also available:

- Perinatal antiretroviral guidelines slide set. AIDS Education and Training Centers (AETC) National Resource Center. 2006 Oct 16. 79 slides. Available from the [AETC Web site](#).

The following is also available:

- A comprehensive Spanish-language Web site featuring information about HIV treatment and clinical trials is available at <http://aidsinfo.nih.gov/infoSIDA/>.

PATIENT RESOURCES

The following is available:

- HIV during pregnancy, labor and delivery, and after birth. Fact sheets. Rockville (MD): Department of Health and Human Services (DHHS); 2006 Aug. 9 p.

Electronic copies: Available in Portable Document Format (PDF) from the [AIDSinfo Web site](#).

Print copies: Available from the Centers for Disease Control and Prevention, National Prevention Information Network (NPIN), P.O. Box 6003, Rockville, MD 20850. Telephone: (800) 458-5231, TTY (800)-243-7012 International number (301)-562-1098. Web site: <http://www.cdcnpin.org>.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

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